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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,535	01/15/2002	Augustine M. Choi	13681-003002	7091

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[REDACTED] EXAMINER

CHOI, FRANK I.

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1616
DATE MAILED: 05/19/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,535	CHOI ET AL.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12/30/2002, 2/3/2003, 3/28/2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 42-47,50 and 53-89 is/are pending in the application.
- 4a) Of the above claim(s) 79-88 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 42-47,50 and 53-89 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11,14</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 79-88 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 79 are directed to a composition comprising at least 98% oxygen gas and an amount of carbon monoxide gas and a method of treating a patient in need of a high concentration of oxygen with said composition. Applicant's originally presented claims were directed to methods and said methods do not require at least 98% oxygen and throughout prosecution of the present Application until the Amendment filed on 2/3/2003 did not require the presence of 98% oxygen. Newly presented claims 79-88 would be classified in 424/613, whereas, claims 42-47,50,53-78, 89 are classified in 424/699. As such, in light of the different search required and separate classification, it appears that prosecution of newly submitted claims 79-88 would constitute an undue burden on Examiner.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 79-88 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1616

Claims 65,66,68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of rats having the disease states and/or conditions specifically treated and treatment specifically related to the mechanisms by which the active components effect said treatment of said disease state and/or condition which are set forth in the examples in pages 16-34 of the Specification, does not reasonably provide enablement for preventing inflammation secondary to sepsis, promoting wound healing or treating arthritis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons of record and the further reasons below.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The prior of record does not appear to show prevention of inflammation secondary to sepsis, promotion of wound healing or arthritis, as such, it does not appear from the prior art that one of ordinary skill in the art could predict that administration of carbon monoxide would be effective in preventing inflammation secondary to sepsis, promoting wound healing or arthritis. Further, the Specification does not appear to provide any working examples in which inflammation secondary to sepsis was prevented, wounds were healed or arthritis treated. It appears that inflammation would be present if sepsis is present, as such, it is uncertain how one of ordinary skill in the art could prevent inflammation if sepsis is already present. Further, Applicant does not appear to have shown how the in vitro or animal data correlates to wound healing or treatment of arthritis. As such, it appears that one of ordinary skill would be required to undue experimentation in order to determine whether carbon monoxide would be able to prevent inflammation secondary to sepsis, promote wound healing or treat arthritis.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65-69,74,89 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements for the reasons of record set forth in the prior Office Action and Interview Summary (12/12/2002) relative to claims 42-69. See MPEP § 2172.01. Examiner has duly considered Applicant's arguments but deems them unpersuasive. In light of the toxic nature of the gases being introduced (which is admitted by Applicant in the response on page 16 (2/3/2003)), the claims should indicate that a "therapeutically" effective amount is administered. Applicant indicated that to move prosecution forward that claims 42,57,58,60-64 would be amended to indicate a "therapeutically effective amount" of the carbon dioxide. However, the above claims which also raise the same issue do not appear to have been amended accordingly. As such, Examiner maintains the rejection herein.

Claims 42-47,50,53-78,89 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 42-78,89 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 13 filed 2/3/2003. In that paper, applicant has stated "none of the publications cited in the Office Action, singly or in combination, teaches or suggests administering inhaled carbon monoxide gas as a therapeutic agent to treat the diseases and conditions recited in the pending claims" (pg. 20), and this statement indicates that the invention is different from what is defined in the claim(s) because the claims do not indicate that the carbon monoxide is administered by inhalation.

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Claim 65 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 recites the limitation "reduce or prevent inflammation". There is insufficient antecedent basis for this limitation in the claim as the preamble indicates that the claim is a "method of treating inflammation".

Claim Rejections - 35 USC §102/ 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (f) he did not himself invent the subject matter sought to be patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 61 is rejected under 35 U.S.C. 102(b) as being anticipated by Campbell (Abstract).

Campbell teaches that inhalation of carbon monoxide retarded development of cancer of the skin and primary adenoma of the lungs in mice.

Claims 60,61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maxwell et al. (Abstract) in view of Campbell (Abstract).

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Maxwell et al. teach that exposure of animals bearing transplantable tumors to carbon monoxide resulted in a decrease in the rate of tumor growth.

Campbell teaches that inhalation of carbon monoxide retarded development of cancer of the skin and primary adenoma of the lungs in mice.

The difference between the claimed invention and the prior art is that the prior art does not expressly disclose the treatment of cancer in a human patient by administering carbon monoxide. However, the prior art amply suggests the same as it is known that it is effective in the treatment of cancer in animals. As such, it would have well within the skill of and one of ordinary skill in the art would have been motivated to use the same in humans with the expectation that inhaled carbon monoxide would be effective in treating cancer in humans.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Examiner directs Applicant's attention to document was found in SCISEARCH database entitled "Exogenous carbon monoxide attenuates aeroallergen-induced eosinophilic inflammation in mice", Chapman et al., American Journal of Respiratory and Critical Care Medicine (March 1999), Vol. 159, No. 3, Supp. Pp. A218-A218. Although, the SCISEARCH document did not contain a complete abstract, Examiner assumes it contains similar material to that disclosed in a later published document under the same title (See Paper No. 13, Exhibit E). Since authors Elias and Chapman are not listed as inventors in the present Application and the date of the document is prior to the priority date. Examiner provisionally rejects claims 57-59,62-65 over said document pursuant to 35 USC 102 (a) and/or (f).

Conclusion

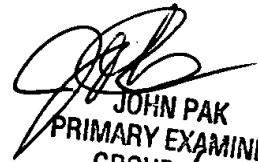
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

May 15, 2003



JOHN PAK
PRIMARY EXAMINER
GROUP 1600

